

REMARKS-General

1. The newly drafted independent claim 26 incorporates all structural limitations of the original claim 1 and includes further limitations previously brought forth in the disclosure. No new matter has been included. All new claims 26 to 48 are submitted to be of sufficient clarity and detail to enable a person of average skill in the art to make and use the instant invention, so as to be pursuant to 35 USC 112.

2. With regard to the rejection of record based on prior art, Applicant will advance arguments to illustrate the manner in which the invention defined by the newly introduced claims is patentably distinguishable from the prior art of record. Reconsideration of the present application is requested.

Response to Rejection of Claims 1-6 and 9-25 under 35USC103

3. The Examiner rejected claims 1-6 and 9-25 over Li in view of the various cited arts. Pursuant to 35 U.S.C. 103:

“(a) A patent may not be obtained though the invention is **not identically** disclosed or described as set forth in **section 102 of this title**, if the **differences** between the subject matter sought to be patented and the prior art are such that the **subject matter as a whole would have been obvious** at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

4. In view of 35 U.S.C. 103(a), it is apparent that to be qualified as a prior art under 35USC103(a), the prior art must be cited under 35USC102(a)~(g) but the disclosure of the prior art and the invention are not identical and there are one or more differences between the subject matter sought to be patented and the prior art. In addition, such differences between the subject matter sought to be patented **as a whole** and the prior art are obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

5. In other words, the differences between the subject matter sought to be patent as a whole of the instant invention and Li which is qualified as prior art of the instant invention under 35USC102(b) are obvious in view of the various cited art at the

time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.

6. The applicant respectfully submits that in order to determine whether the differences between the subject matters sought to be patent as a whole of the instant invention and the primary prior art, Li, are obvious in view of the supplemental cited arts, Song, Jiang, Wang, Chen, Hsu, Takahashi, Grayer-Berkmeijer, Yoshikawa, Somava, Li et al, and/or Prasad, we have to identify all the differences between the claims of the instant inventions and Li. The applicant respectfully identifies the differences between the claims of the instant invention and Li as follows:

(a) Referring to the newly amended claim 26, the composition is used for treating living object with non-insulin dependent diabetes mellitus by restoring insulin beta cells, whereas Li merely teaches a tablet for lowering blood sugar. A mere recitation of providing a blood sugar-lowering tablet does not in any way anticipate or suggest any composition for treating living object with non-insulin dependent diabetes mellitus ***through restoration of insulin beta cells***. Experiments have shown a promising effect of restoring insulin beta cells by administering berberine and catalpol. This is an ***unexpected result*** from combining the two active ingredients. Lowering of blood glucose level can be accomplished by many methods such as beta cells stimulation for extra secretion of insulin, or artificial synthesis of insulin. Li and the related cited arts do not in any way teach, suggest or motivate the use of the two claimed active ingredients for lowering blood glucose level ***through restoration of insulin beta cells*** in living objects such as mice.

(b) In the newly amended claim 26, "the composition comprises a berberine as a first active ingredient and a catalpol as a second active ingredient". Li merely teaches the traditional Chinese medicine is selected from astragalus root, Ginseng, figwort, Chinese yam, medlar, radices rehmanniae, cortex lycii radices, radices puerarrie, rhizome polygonati, scutellaria, Phellodendron rupr, pieplant, fructus schizandrae, honeysuckle, rhizome anemarrhenae, rhizome attractylodis, radices polygonati, officinalis, truckahoe, lily, radices trichosanthis, etc. However, Li fails to teach any composition comprising berberine and catalpol and the combined effect of these ingredients.

The Examiner alleges that Phellodendron and Rehmannia are known to be sources of the first and second active ingredients. The applicant respectfully submits that Phellodendron and Rehmannia contain different kinds of compositions and that the medicine containing Phellodendron and Rehmannia is not equivalent to the composition of the instant invention containing berberine and catalpol. The only suggestion of Chinese medicine in Li is selected from Phellodendron, Rehmannia, etc.... Besides, Li does not verbally suggest any extraction of berberine and catalpol from Phellodendron and Rehmannia not the step of extracting the berberine and catalpol from Phellodendron and Rehmannia.

(c) Li fails to teach composition further comprises an oleanolic acid as a third active ingredient as claimed in the newly amended claim 27 in addition to what is claimed in claim 26 as a whole. Accordingly, a mere recitation of providing honeysuckle does not anticipate or suggest any composition containing oleanolic acid. In other words, Li does not disclose what kinds of composition can be extracted from Phellodendron, Rehmannia, and honeysuckle to obtain berberine, catalpol, and oleanolic acid and how the Phellodendron, Rehmannia, and honeysuckle uses for treating living object with non-insulin dependent diabetes mellitus. Moreover, Li and the cited arts do not teach, suggest, or motivate the use of Phellodendron, Rehmannia and Lonicera to lower blood glucose level **by restoration of insulin beta cells** in a living object.

(d) Li fails to teach the berberine is extracted from one or more natural herbs selected from the group consisting of Berberis, Chelidonium, Stephniz, Coptis, Phellodendron, and Ziziphus as claimed in claims 28 and 31 in addition to what is claimed in claim 26 as a whole. Li merely suggests the tablet contains Phellodendron without teaching any berberine extracted from Phellodendron. In fact, the instant invention discloses berberine can be extracted from one or more natural herbs of Berberis, Chelidonium, Stephniz, Coptis, Phellodendron, and Ziziphus.

(e) Li fails to teach the catalpol is extracted from one or more natural herbs selected from the group consisting of Rehmannia, Verbascum, Paulownia, Globularia, and Adonis as claimed in the newly amended claims 29 and 31 in addition to what is claimed in claim 26 **as a whole**. Li merely suggests the tablet contains Rehmannia without teaching any catalpol extracted from Rehmannia.

(f) Li fails to teach the oleanolic acid is extracted from one or more natural herbs selected from the group consisting of Olea, Swertia, Astringia, Lonicera, and Beta as claimed in the newly amended claim 30 in addition to what is claimed in the newly amended claim 26 as a whole. Li merely suggests the tablet contains honeysuckle without teaching any oleanolic acid extracted from honeysuckle.

(g) Li fails to teach the composition is prepared into a predetermined form for administration that contains 1 to 300 mg/kg/dl of berberine for treating living object with non-insulin dependent diabetes mellitus as claimed in claims 32 and 33 in addition to what is claimed in claim the newly amended claim 26 as a whole. Li is silent regarding any ratio of berberine for administration by living object. The disclosed dose is effective in helping restoration of insulin beta cells.

(h) Li fails to teach the composition is prepared into a predetermined form for administration that contains 5 to 1500 mg/kg/dl of berberine for treating living object with non-insulin dependent diabetes mellitus as claimed in the newly amended claim 34 in addition to what is claimed in claim 26 as a whole. Li is silent regarding any ratio of berberine for administration by living object.

(i) Li is silent regarding the composition is prepared as a draught in water for treating living object as claimed in claims 35 and 44 in addition to what is claimed in the newly amended claim 26 as a whole. Li merely teaches a tablet has blood sugar lowering effect.

(j) Li is silent regarding the composition is prepared as a syrup for treating living object as claimed in the newly amended claims 36 and 45 in addition to what is claimed in the newly amended claim 26 as a whole.

(k) Li is silent regarding the composition is prepared as a cachets for treating living object as claimed in newly amended claims 37 and 46 in addition to what is claimed in the newly amended claim 26 as a whole.

(l) Li is silent regarding the composition is prepared as a tablet for treating living object as claimed in the newly amended claims 38 and 47 in addition to what is claimed in the newly amended claim 26 as a whole.

(m) Li is silent regarding the composition is prepared as a solution for treating living object as claimed in the newly amended claims 39 and 48 in addition to what is claimed in the newly amended claim 26 as a whole.

(n) Li fails to teach the composition is prepared into a predetermined form for administration that contains 1 to 300 mg/kg/dl of the active ingredients as claimed in claims 40 to 43 in addition to what is claimed in the newly amended claim 26 as a whole.

7. Furthermore, the applicant respectfully submits that when applying 35 USC 103, the following tenets of patent law must be adhered to:

- (a) The claimed invention must be considered as a whole;
- (b) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (c) The references must be viewed without the benefit of hindsight vision afforded by the claimed invention; and
- (d) Reasonable expectation of success is the standard with which obviousness is determined.

8. Also, "The mere fact that a reference could be modified to produce the patented invention would not make the modification obvious unless it is suggested by the prior art." Libbey-Owens-Ford v. BOC Group, 4 USPQ 2d 1097, 1103 (DCNJ 1987).

9. Song, Jiang, Wang, Chen, Hsu, Takahashi, Grayer-Berkmeijer, Yoshikawa, Somava, Li et al, and/or Prasad merely teach the individual component without providing a composition including berberine, catalpol, and oleanolic acid for treating living object with non-insulin dependent diabetes mellitus **through restoration of beta cells**. Generally speaking, most Chinese medicines contain two or more ingredients combining with each other to minimize the side effect of each ingredient. For example, berberine itself is toxicity and may cause heart disease and lower the blood pressure. The composition of berberine, catalpol, and oleanolic acid can minimize the side effect of berberine and allows the living object, especially for human being, for administration. In fact, neither Li, Song, Jiang, Wang, Chen, Hsu, Takahashi, Grayer-Berkmeijer, Yoshikawa, Somava, Li et al, nor Prasad suggests a method of treating a

living object for administration containing the above distinctive features (a) to (n) as claimed in the instant invention as well as any combination or possibility of providing a composition including berberine, catalpol, and oleanolic acid for treating living object with non-insulin dependent diabetes mellitus. The unexpected results in the instant invention should therefore be recognized.

10. "To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited art references for combination in the manner claimed... [T]he suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness..." *In re Gorman*, 933 F.2d 982, 986, 18 USPQ 2d 1885, 1888 (Fed. Cir. 1991).

11. Accordingly, the applicant believes that neither Li, Song, Jiang, Wang, Chen, Hsu, Takahashi, Grayer-Berkmeijer, Yoshikawa, Somava, Li et al, nor Prasad, separately or in combination, suggests or makes any mention whatsoever of the difference subject features (a) to (n) as claimed in the amended claims 26-31 and 32-48 of the instant invention.

12. Applicant believes that for all of the foregoing reasons, all of the claims are in condition for allowance and such action is respectfully requested.

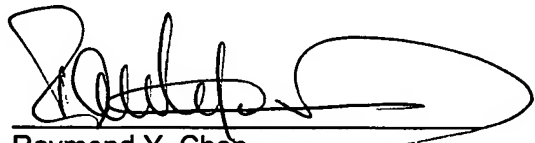
The Cited but Non-Applied References

13. The cited but not relied upon references have been studied and are greatly appreciated, but are deemed to be less relevant than the relied upon references.

14. In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of the rejection are requested. Allowance of claims 26-31 and 32-48 at an early date is solicited.

15. Should the Examiner believe that anything further is needed in order to place the application in condition for allowance, he is requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

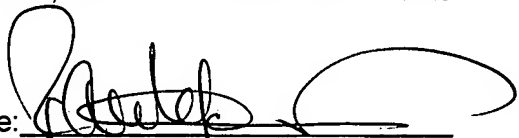


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